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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,850	11/19/2001	John F. Gordon	111465-128	7587

20995 7590 07/28/2005

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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/988,850		GORDON ET AL.	
	Examiner		Art Unit	
	Nelson Yang		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 10-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 7, 20, and 21 is acknowledged and has been entered.
2. Applicant's cancellation of claims 8 and 9 is acknowledged and has been entered.
3. Claims 1-7 and 10-28 are currently pending.
4. Claims 1-6 have been withdrawn.

Rejections Withdrawn

5. Applicant's arguments, see 11-12, filed May 11, 2005, with respect to Virtanen [US 6,030,581] in view of Burd [US 5,518,930] and of Virtanen [US 6,030,581] in view of Burd [US 5,518,930], and further in view of Chow [US 6,167,910], have been fully considered and are persuasive. The rejections of claims 7-10, 16-23 with respect to Virtanen [US 6,030,581] in view of Burd [US 5,518,930] and of claims 14, 15, 27, 28 with respect to Virtanen [US 6,030,581] in view of Burd [US 5,518,930], and further in view of Chow [US 6,167,910] have been withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7, 10-13, 16-19, and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742] in view of Virtanen [US 6,030,581].

With respect to claims 7, 20, 21, 23, Coleman teaches an analyte test container comprising a separation chamber (reception chamber) with an inlet formed when a closure is pushed down to rupture membrane 302 and, a filter means in fluid connection with the separation chamber (fine mesh filter, 312), multiple mixing chambers (chambers with mixing means, 314 and 316) in direct fluid communication with the separation chamber and not in direct fluid communication with each other, and multiple detection chambers (cuvettes, 328 and 330) (figs. 22, col. 13, lines 21-57). Coleman, however, fails to teach that the container is configured to be capable of being rotated and transferring fluid from chamber to chamber in response to the rotation of the container, or the presence of capture zones and of second and third inlet ports for introducing material from a source other than the separation chamber.

Virtanen, however, does teach chambers can be located on an optical disc for assays, along with software on the disk associated with an assay for a particular analyte or analytes (column 4, lines 25-31). Virtanen teaches that such optical discs allow for assays to be performed quickly efficiently, accurately and at low cost, by combining diagnostic assays with computers and compact disk technology (column 1, lines 48-59). Coleman further teaches that this embodiment of chambers allow for stepwise addition and control of reaction sequences by using the preferred Gochman method for the determination of uric acid (column 14, lines 20-25). Virtanen also teaches that sample preparation chambers, such as the chambers with mixing means of Coleman, may contain preloaded reagents or that reagents stored in separate chambers may mix with the sample when it arrives in the sample preparation chamber to prepare the sample for an assay in the cuvettes (detection chamber) (column 10, lines 19-35). Virtanen further teaches that analytes bind to predetermined regions on the disk, allowing for

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identification of a particular analyte with the location at which it is bound (column 5, lines 45-52).

Therefore, it would have been obvious for the analyte test container of Coleman to be adapted to an optical disc, as suggested by Virtanen, in order to allow for assays to be performed quickly efficiently, accurately and at low cost, and furthermore to provide an embodiment in the optical disk of Virtanen that would be capable of stepwise addition and control of reaction sequences using the preferred Gochman method for the determination of uric acid. It would have also have been obvious to have had second and third inlet ports connected to the mixing chambers and configured to deliver reagents to the mixing chambers, in order to prepare samples for assays in the cuvettes. It would further have been obvious to include capture zones, where analytes bind to predetermined regions on the disk, in order to allow for identification of a particular analyte with the location at which it is bound.

8. With respect to claims 10-13, 22, 24-26, Virtanen teaches that the bio-disc can be made from two halves, where the lower half may contain all the components (column 4, lines 62-67) and a upper half comprises a cover containing only a few components such as electrodes and wires. The components may be glued or melted together (column 5, lines 3-6).

9. With respect to claims 16-19, Virtanen teaches chambers can be located on an optical disc for assays, along with software on the disk associated with an assay for a particular analyte or analytes (column 4, lines 25-31). Virtanen further teaches that a reflective element can be used to monitor liquid flow during the assay (column 7, lines 9-20), such as reflective gold spheres or opaque latex spheres (column 8, lines 50-55).

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10. Claims 14, 15, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman [US 3,799,742], in view of Virtanen [US 6,030,581], as applied to claims 7, 20 above, and further in view of Chow [US 6,167,910].

With respect to claims 14-15, 27-28, Coleman and Virtanen teach the use of a cap and substrate, as discussed above. Coleman does not teach the use of a channel layer, with separation, mixing, and detection chambers formed in the channel layers. While Virtanen teaches that capillary ducts and fluid storage and retention compartments may be formed by chemical means or in injection molding operations, Virtanen does not specifically teach a channel layer bonded between the cap and substrate.

Chow, however, does teach the use of multi-layered channels and chambers. Chow further teaches that providing multi-layered channel structures and networks and taking advantage of both surfaces of planar substrates, optimal use of substrate materials is permitted, allowing further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation (col.3, lines 10-26).

Therefore it would have been obvious in the device of Coleman and Virtanen to have a channel layer, with separation, mixing, and detection chambers formed in the channel layer, as suggested by Chow, in order to allow further miniaturization of fluidic processes and providing cost advantages in terms of substrate conservation.

Response to Arguments

11. Applicant's arguments with respect to claims 7 and 10-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

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12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

07/24/05